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Dkt. 60772-PCT-US/JPW/GJG/CSN

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Rina Aharoni et al. Examiner: A. De Cloux

U.S. Serial No.: 09/768,872 Group Art Unit: 1644

Filed : January 23, 2001

For : TREATMENT OF AUTOIMMUNE CONDITIONS WITH COPOLYMER 1 AND RELATED COPOLYMERS.

1185 Avenue of the Americas
New York, New York 10036
May 28, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

COMMUNICATION IN RESPONSE TO MARCH 26, 2002 OFFICE ACTION, SUBSTITUTE SEQUENCE LISTING AND PETITION FOR ONE-MONTH EXTENSION OF TIME

This Communication is submitted in response to the March 26, 2002 Office Action in connection with the above-identified application. A response to the March 26, 2002 Office Action was due April 26, 2002. Applicants hereby petition for a one-month extension of time under 37 C.F.R. §1.136(a)(1) from April 26, 2002 to May 26, 2002. However, since May 26, 2002 falls on a Sunday, the next succeeding day which is not a Saturday, Sunday or Federal holiday, i.e., Tuesday, May 28, 2002, is considered timely under 37 C.F.R. § 1.7. Accordingly, this Communication is being timely filed.

On pages 1-2 of the March 26, 2002 Office Action, after alleging that the Preliminary Amendment filed on January 23, 2001 had not been entered, the Examiner entered a restriction requirement between claims defining the following allegedly independent and distinct inventions:

98

I. Claims 1-4, 16-20 and 32-39, drawn to a terpolymer consisting essentially of tyrosine, alanine and lysine randomly polymerized into a polypeptide, and a pharmaceutical composition thereof for treating an autoimmune disease;

II. Claims 5-8, 16, 21-24 and 32-39, drawn to a terpolymer consisting essentially of tyrosine, glutamic acid and lysine randomly polymerized into a polypeptide, and a pharmaceutical composition thereof for treating an autoimmune disease;

III. Claims 9-12, 16, 25-28 and 32-39, drawn to a terpolymer consisting essentially of glutamic acid, alanine and lysine randomly polymerized into a polypeptide, and a pharmaceutical composition thereof for treating an autoimmune disease;

IV. Claims 13-16, 29-39, drawn to terpolymer consisting essentially of tyrosine, alanine and glutamic acid randomly polymerized into a polypeptide, and a pharmaceutical composition thereof for treating an autoimmune disease;

V. Claims 40-41, drawn to a method of treating an autoimmune disease comprising administering a terpolymer, wherein said terpolymer polypeptide, comprising three different amino acids randomly polymerized into a polypeptide, wherein said three amino acids are tyrosine, alanine and lysine;

VI. Claims 40 and 42, drawn to a method of treating an autoimmune disease comprising administering a

terpolymer, wherein said terpolymer polypeptide, comprising three different amino acids randomly polymerized into a polypeptide, wherein said three amino acids are tyrosine, glutamic acid and lysine;

VII. Claims 40 and 43, drawn to a method of treating an autoimmune disease comprising administering a terpolymer, wherein said terpolymer polypeptide, comprising three different amino acids randomly polymerized into a polypeptide, wherein said three amino acids are glutamic acid, alanine and lysine;

VIII. Claims 40 and 44, drawn to a method of treating an autoimmune disease comprising administering a terpolymer, wherein said terpolymer polypeptide, comprising three different amino acids randomly polymerized into a polypeptide, wherein said three amino acids are tyrosine, alanine and glutamic acid;

IX. Claim 45, drawn to a method for treating an autoimmune disease which comprises administering a polypeptide consisting essentially of amino acids tyrosine, glutamic acid, alanine and lysine, wherein the autoimmune disease is not multiple sclerosis; and

X. Claim 134 (renumbered as claim 46), drawn to a kit comprising a water soluble MHC protein, a reaction chamber and a means for detecting binding of the analyte to the MHC protein and a container.

The Examiner noted that claim 46 was originally filed as claim 134, but has been renumbered as claim 46 in accordance with Rule 1.126.

The Examiner alleged that the inventions are distinct, each from the other because Inventions V-IX are allegedly unique methods, because although each method has the same endpoint, each method allegedly comprises administering different ingredients. Therefore, the Examiner alleged that Groups V-IX are patentably distinct.

The Examiner also alleged that Inventions I-IV and Group X are unique products because each allegedly has a different structure with distinct biophysical properties. Therefore, the Examiner alleged that Groups I-IV and X are patentably distinct.

In addition, the Examiner alleged that Groups I-IV and Groups V-VIII, respectively, are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product, referring to M.P.E.P 806.05(h). In the present case, the Examiner alleged that the product as claimed, the terpolymer, can be used in a method of affinity purification, as well as in the recited method of treating an autoimmune disease.

The Examiner further alleged that because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their allegedly recognized divergent subject matter, and because a search in the non-patent literature of any of these distinct inventions allegedly would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would allegedly constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is allegedly proper.

In addition, on page 4 of the March 26, 2002 Office Action, the Examiner instructed that if one of Inventions I-IX is elected, applicants must elect a specific autoimmune disease, e.g., multiple sclerosis.

Specifically, the Examiner alleged that claims 1-16 and 32-46 are generic in at least one aspect.

The Examiner also alleged that the species are distinct each from the other because autoimmune diseases differ with respect to their etiology and symptoms.

In reply, applicants first point out that although the March 26, 2002 Office Action indicates that the Preliminary Amendment filed January 23, 2001 was not entered, in an April 2, 2002 telephone conference between Examiner DeCloux and Christine S. Nickles of the undersigned attorney's office, the Examiner stated that the January 23, 2001 Preliminary Amendment had been entered except for the deletion of the claim to the benefit of U.S. Provisional Application No. 60/123,675, filed March 9, 1999. To remove the claim to the benefit of U.S. Provisional Application No. 60/123,675, applicants submitted on August 31, 2001 a new Declaration and Power of Attorney, which did not recite a claim to the benefit of U.S. Provisional Application No. 60/123,675.

In response to the Restriction Requirement, applicants hereby elect with traverse Invention I, i.e., claims 1-4, 16-20 and 32-39, drawn to a terpolymer consisting essentially of tyrosine, alanine and lysine randomly polymerized into a polypeptide, and a pharmaceutical composition thereof for treating an autoimmune disease. In addition, applicants hereby elect with traverse multiple sclerosis as the specific autoimmune disease.

Applicants request that the Examiner reconsider and withdraw the restriction requirement with respect to Inventions I-IX. Applicants respectfully direct the Examiner's attention to 35 U.S.C. §121, which states, in part, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicants request that the restriction requirement be withdrawn with respect to Inventions I-IX because the Inventions I-IX are not independent of each other.

Under M.P.E.P. §802.01, "independent," means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation and effect." Applicants maintain that there is a disclosed relationship between Inventions I-IX. This relationship, as disclosed on page 1, lines 22-33 of the specification, is that all of the terpolymers used in Inventions I-VIII consist essentially of three of the four amino acids in Copolymer 1 (Invention IX) and are used to treat autoimmune diseases. Thus, there is a disclosed relationship between each of the terpolymers, the pharmaceutical compositions comprising them and methods of treating autoimmune diseases by administering the terpolymers and by administering Copolymer 1. Accordingly, the restriction requirement should be withdrawn with respect to Inventions I-IX.

Furthermore, under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. Applicants assert that the withdrawal of the restriction requirement with respect to Inventions I-IX would not impose a serious burden on the search or examination. A search of the prior art regarding

a terpolymer and pharmaceutical compositions comprising the terpolymer (Inventions I-IV) would also reveal prior art concerning uses of the pharmaceutical compositions, including treatment of autoimmune diseases (Inventions V-VIII). Additionally, a prior art search for one terpolymer and pharmaceutical compositions comprising that terpolymer (Inventions I-IV) would bring to light prior art concerning the other terpolymers and pharmaceutical compositions comprising them because each terpolymer consists essentially of three of the four amino acids in Copolymer 1. That same prior art search for a given terpolymer and pharmaceutical compositions comprising the terpolymer (Inventions I-IV) would locate prior art concerning methods of treating autoimmune diseases by the administration of Copolymer 1 (Invention IX) because terpolymers consist essentially of three of the four amino acids in Copolymer 1 and are used for the same purpose of treating autoimmune diseases. Given that it would not be a serious burden on the Examiner if restriction were not required, the restriction requirement should be withdrawn with regard to Inventions I-IX.

For all of the above reasons, applicants respectfully requests that the Examiner reconsider and withdraw the restriction requirement with regard to Inventions I-IX.

At a minimum, applicants contend that, since they have elected Invention I, Invention I should be combined with Invention V, which is a method of using Invention I. Applicants respectfully direct the Examiner's attention to 37 C.F.R. §1.141(b), which states, "If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product, even though a showing of distinctness between the product and the process of using the product can be made." Applicants are not

claiming a process of making, so when the rule is applied to the subject application, it indicates that, the process of using (Invention V) may be joined with the claims directed to the product (Invention I), even if a showing of distinctness between the product and the process of using the product can be made, as the Examiner has alleged.

Applicants respectfully point out that if Invention V is not examined with Invention I, if the product claims of Invention I are allowed, a use of the claimed product must be included in the same application. Applicants respectfully direct the Examiner's attention to MPEP §806.05(i), which states, "Where the product claims are allowable (i.e., novel and nonobvious), restriction may be required only where the process of making and the product made are distinct (MPEP §806.05(f)); otherwise the process of using must be joined with the process of making and product made, even if a showing of distinctness can be made between product and process of using (MPEP §806.05(h))" (emphasis added). The MPEP indicates if the product claims are allowable, the only case in which a restriction would be appropriate is where the process of making and the product made are distinct. Applicants are not claiming a process of making. Therefore, if the product claims of Invention I are allowed, then claims to the use of the product (Invention V), must be joined with the product claims. Rather than solely examining Invention I and then adding Invention V back after the allowance of Invention I, applicants respectfully request that, at a minimum, the Examiner join Invention I with Invention V. If, however, the Examiner upholds the restriction requirement in its entirety, applicants respectfully request that the Examiner at least acknowledge that if the claims of Invention I are allowed, she will then consider the claims of Invention V in the same application.

SUBSTITUTE SEQUENCE LISTING

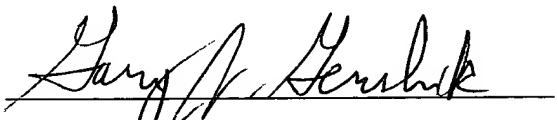
Applicants submit as **Exhibit A** hereto substitute sheets of the "Sequence Listing." Applicants are submitting substitute sheets of the "Sequence Listing" to delete the claim to the benefit of the filing date of U.S. Provisional Application 60/123,675, filed March 9, 1999, the benefit of which applicants are no longer claiming. Applicants also submit a computer readable form (CFR) copy of the substitute sheets of the "Sequence Listing." Applicants note that all sequences in the subject application are identified by sequence identification numbers (SEQ ID Nos), so an amendment directing the entry of the "Sequence Listing" into the application is unnecessary. In addition, applicants submit as **Exhibit B** hereto a Statement in Accordance with 37 C.F.R. § 1.825(b), certifying that the content of the "Sequence Listing" in computer readable form is identical to the paper copy of the "Sequence Listing". The Statement in Accordance with 37 C.F.R. §1.825(b) (**Exhibit B**) also certifies that the computer readable form and the substitute sheets of the "Sequence Listing" include no new matter.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone the number provided below.

No fee, other than the $110.00 fee for the one-month extension of time for responding to the March 26, 2002 Office Action, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required,

authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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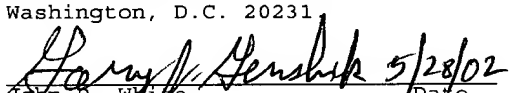
I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.



5/28/02
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